IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **WAVE 3 CASES LISTED IN DEFENDANTS' EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' RESPONSE TO DEFENDANTS' WAVE 3 MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF PAUL J. MICHAELS, M.D.

Dr. Paul Michaels has been practicing pathology for nearly two decades, is subspecialized in gynecological pathology and is board certified in clinical pathology, anatomical pathology and cytopathology. Exhibit A – Wave 3 Expert Report of Paul J. Michaels, M.D. at p. 1; Exhibit B - Curriculum Vitae of Paul J. Michaels, M.D at 2-3. Prior to being retained as an expert in these cases, Dr. Michaels analyzed approximately 24 explanted polypropylene pelvic mesh devices and has analyzed several additional Ethicon mesh explants in the context of this litigation. Exhibit C – General Opinion Deposition of Dr. Michaels, 6/18/2016 at 13:2-14:2; 14:4-17; 52:4-13; 53:9-54:2; 54:8-55:11. He has far more pre-litigation, mesh-specific experience than many of the expert pathologists designated by Ethicon in these cases, such as Dr. Longacre who had only analyzed 6 mesh explants prior to her involvement in this litigation or Dr. Stephen Factor who had never analyzed a single explanted mesh specimen before he was retained by the Defendants. Exhibit D – Deposition of Dr. Terri Longacre, 12/19/14, at 45:3-8; Exhibit E - Deposition of Dr. Factor, 11/27/2012 at 19:13-18.

Despite this, the Defendants challenge Dr. Michaels' qualifications and the reliability of

his opinions in these Wave 3 cases. To achieve this, the Defendants wholly misrepresent Dr. Michaels' opinions and testimony by using incomplete "snippets" of testimony and then engage in an exercise of "gotcha" in an effort to twist Dr. Michaels' testimony into a basis for exclusion rather than soundly challenging his well-founded and reliable opinions. Such efforts by Defendants must fail.

Contrary to Ethicon's misrepresentations, Dr. Michaels is highly qualified to offer his general opinions and testimony concerning: (1) the propensity for Ethicon's Prolene polypropylene mesh material to undergo *in vivo* degradation, (2) complications associated with the *in vivo* degradation process; (3) *in vivo* mesh contraction, shrinkage and deformation; and (4) the associated complications caused by Ethicon's Prolene polypropylene pelvic mesh devices, including inflammation, scarring, nerve entrapment, erosions, chronic pain and dyspareunia to name a few. Moreover, Dr. Michaels' opinions are reliably based on a combination of:

1) His personal experience as a board-certified pathologist;
2) His frequent interactions with clinical colleagues in the day-to-day management of patients;
3) Various internal Ethicon documents;
4) Peer-reviewed publications; and
5) Depositions of Ethicon's employees.

As such, the Defendants' motion to exclude the general opinion testimony of Dr. Michaels should be denied as he possesses the requisite qualifications to offer his general opinions which are based on reliable methodologies that he reliably applied to the facts of the case.

BACKGROUND AND QUALIFICATIONS

Dr. Paul Michaels is board certified by the American Board of Pathology in Anatomic Pathology, Clinical Pathology, and Cytopathology. Exhibit A at p. 1; Exhibit B. Dr. Michaels has a strong subspecialty focus in breast and gynecologic pathology, as well as cytopathology. Exhibit A at 1. He received his medical degree from the University of California, Los Angeles School of Medicine and completed his residency in anatomic and clinical pathology at Massachusetts General Hospital, an affiliate of Harvard School of Medicine where he was a Clinical Fellow in Pathology and also where he completed his residency in Cytopathology. *Id*.

Dr. Michaels is presently the Laboratory Director for two separate Stat clinical laboratories in the Austin, Texas area, both of which are affiliated with Clinical Pathology Laboratory/Sonic Healthcare USA, the third largest pathology company in the United States. *Id*. He is currently affiliated with Clinical Pathology Associates in Austin, Texas and has privileges at numerous medical centers. *Id*.

During Dr. Michaels' medical training, he was educated and trained on the tissue response to foreign bodies generally. Exhibit C at 14:21-15:2. Moreover, before he was retained as an expert witness by the plaintiffs in this litigation, Dr. Michaels had previously analyzed approximately 24 explanted polypropylene pelvic mesh specimens and frequently analyzing explanted polypropylene sutures specimens to determine the extent to which the polypropylene material contributed to his pathological findings, including the tissue response, foreign body reaction, fibrotic response and *in vivo* degradation observed by him macroscopically and microscopically using the same histology methods employed by experts within the pathology field. *Id*. at 13:2-14:2; 14:4-17; 52:4-13; 53:9-54:2; 54:8-55:11.

ARGUMENT

Plaintiffs incorporate by reference the standard of review for *Daubert* motions articulated by the Court in *Edwards v. Ethicon,* 2014 U.S. Dist. Lexis 92316 (S.D. W. Va. 2014).

I. Dr. Michaels Is Highly Qualified to Offer His Sound Medical and Scientific Opinion That Ethicon's Prolene Polypropylene Mesh Undergoes *In Vivo* Degradation.

Throughout the Defendants' brief, they attempt to paint an inaccurate picture of Dr. Michaels' opinions and the methodology employed by him. For example, the Defendants argue that Dr. Michaels' pre-litigation degradation opinions are limited to "his general belief" that polypropylene sutures degrade and are based on nothing more than "general discussions" he had in the past. Def. Br. at 4. Contrary to the Defendants' representation, Dr. Michaels testified that he learned that polypropylene sutures can undergo *in vivo* degradation from reading published literature. *Id*. at 52:4-12 .

The Defendants also argue that Dr. Michaels' testimony "demonstrates that his experience has not provided him with the specialized knowledge necessary to offer" his general opinion that Ethicon's mesh products degrade *in vivo* Def. Bf. at 4. In support of this argument, Defendants incorrectly assert that Dr. Michaels' experience with analyzing 24 explanted polypropylene mesh devices prior to his involvement in this litigation was limited to his gross analysis only. Def. Br. at 5. However, Dr. Michaels testified that he analyzed these explanted polypropylene pelvic mesh specimens using both gross and microscopic histology techniques. Exhibit C at 12:8-13:1; 53:18-54:2; 54:8-19; 55:12-56:9.

As Dr. Michaels' deposition testimony illustrates, he is sufficiently qualified as a board certified pathologist with considerable mesh-specific experience to offer his general

degradation opinions. *See, e.g.*, *Frankum v. Bos. Sci. Corp*., No. 2:12-CV-00904, 2015 WL 1976952, at *24 (S.D. W. Va. May 1, 2015) (finding that an anatomical and clinical pathologist is qualified to testify about pathology of mesh material despite an apparent lack of training in polymer science or testing of mesh products). As such, the Defendants' argument should be rejected.

Ethicon further argues that Dr. Michaels' degradation opinions are based solely on his general pathology experience. Def. Br. at 4. But a review of Dr. Michaels' expert report and his deposition testimony clearly shows that Dr. Michaels bases his degradation opinions, in large part, on his thorough review of the peer-reviewed published literature, Ethicon's internal corporate documents, depositions of Ethicon's employees, his experience as a board-certified clinical and anatomical pathologist and his personal experience analyzing explanted polypropylene pelvic mesh and suture specimens. See Exhibit A –at pp 1-7. See also Exhibit C at 15:15-16:18; 20:12-21:1; 39:2-11; 39:21-40:17; 40:6-41:9; 48:9-49:10; 49:17-18; 52:4-12; 57:9-24; 60:14-20; 63:2-12; 64:9-65:10; 65:21-66:5; 72:15-18; 76:14-77:13; 82:5-19; 103:11-104:4.

Tellingly, in a separate section of its own brief just 4 pages after suggesting that Dr. Michaels' degradation opinions are solely based on his general pathology experience, Ethicon dedicates approximately 4 pages criticizing some of the peer-reviewed degradation publication that Dr. Michaels relied upon in formulating his opinions and nearly 3 additional pages criticizing internal Ethicon studies also relied upon by Dr. Michaels. Thus, the Defendants' own brief demonstrates that Dr. Michaels relied on more than just his general pathology experience and illustrates the lengths at which Ethicon will go to win an argument by mischaracterizing Dr. Michaels' opinions and the methodology he employed in these cases. Compare Def. Br. at p. 4 to Def. Br. at pp. 8-13.

Despite Ethicon's numerous misrepresentations, Dr. Michaels is well qualified to offer his scientifically sound opinions concerning Prolene's propensity to undergo *in vivo* degradation. Indeed, this Court has routinely denied similar challenges made against other pathologists who used the same methods employed by Dr. Michaels here. *See Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, *5–9 (S.D. W. Va. 2014), (c*iting Sanchez, et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *19–20 (S.D. W. Va. Sept. 29, 2014) (ruling that pathologist, Dr. Richard W. Trepeta, was qualified to offer general opinions concerning the properties of polypropylene mesh, including opinions related to mesh degradation, mesh shrinkage, and mesh migration); *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 621 (S.D. W. Va. 2013) ("Bard argues that Dr. Klosterhalfen is not qualified to opine on causation, and that the basis for his opinions is unreliable. Dr. Klosterhalfen's very job as a pathologist qualifies him to opine on this issue [of causation]."), and Dr. Zheng in *Huskey v. Ethicon, Inc., 2:12-cv-05201, 2014 U.S. Dist. LEXIS 92317, 2014 WL 3362264, at *34 (S.D. W. Va. July 8, 2014)* (ruling that Dr. Zheng, [*54] a pathologist, is qualified "to tell the jury the clinical reasons why patients such as Mrs. Huskey require excision of [their mesh devices]")). *See also, Bellew v. Ethicon,* Inc. et al., The United States District Court, Southern District of West Virginia, MDL NO. 2327; 2:12-cv-22473 Charleston, WV, USA (March 5, 2015) at * 28 in which the Court adopts the same language from *Eghnayem. Carlson v. Boston Scientific Corp*., No. 2:12-cv-05762, at *51, *available at* 2015 WL 1931311 at *29 (S.D. W. Va. 2015) (finding pathologist, Dr. Trepeta, qualified to offer general opinions concerning mesh degradation, mesh shrinkage, and mesh migration); *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, *15–19 (S.D. W. Va. 2014), (discussing Dr. Richard Trepeta); *Bellew v. Ethicon*, No. 2:13-cv-22473 (S.D. W. Va. Nov. 20, 2014) [Doc. #265] (permitting pathologist, Dr. Robboy, to offer opinions regarding mesh at issue in case based on his comparison to what he

viewed as typical mesh explants based on his clinical experience). This Court should likewise deny the Defendants' baseless challenges of Dr. Michaels' well-founded degradation opinions.

A. Dr. Michaels' opinions concerning degradation, embrittlement and loss of mechanical properties are reliable.

The Defendants argue that Dr. Michaels' opinions concerning degradation, embrittlement and loss of mechanical properties are unreliable because – according to them – Dr. Michaels did not perform various chemical testing generally conducted by polymer scientists such as Fourier transform infrared spectroscopy ("FTIR"), scanning electron microscopy ("SEM"), gel permeation chromatography, and tensile strength testing. This Court has routinely denied similarly motions by Ethicon and other mesh manufacturing defendants who have sought to exclude similar degradation opinions by various experts who likewise did not conduct the types of chemical tests the Defendants argue are necessary here.

In *Edwards,* Ethicon made an identical argument when it sought to exclude Dr. Iakovlev. *Edwards v. Ethicon,* 2014 U.S. Dist. Lexis 92316, *43 (S.D. W. Va. 2014). In denying Ethicon's motion, this Court held that "Dr. Iakovlev is a pathologist, not a materials scientist. He makes determinations by processing and analyzing explants from the human body….the process Dr. Iakovlev used to analyze the explant is the industry standard in pathology." Dr. Michaels is also pathologist, not a polymer scientist, who specializes in the pathological analysis of explanted tissue and foreign bodies. Like Dr. Iakovlev, Dr. Michaels uses polarized light microscopy and other histology techniques standard in his field.

In addition to his pathology experience, Dr. Michaels relied on the peer-reviewed publications and Ethicon's internal documents. Exhibit C at 15:15-16:18; 20:12-21:1; 39:2-11; 39:21-40:17; 40:6-41:9; 48:9-49:10; 49:17-18; 52:4-12; 57:9-24; 60:14-20; 63:2-12; 64:9-65:10; 65:21-66:5; 72:15-18; 76:14-77:13; 82:5-19; 103:11-104:4. See also Exhibit A at 6. Far

from reaching conclusory or unsupported opinions, Dr. Michaels details his degradation opinions, supporting each such opinion with citations to published literature as well as internal Ethicon degradation testing.

In *Bellew v. Ethicon*, Inc. et al., The United States District Court, Southern District of West Virginia, MDL NO. 2327; 2:12-cv-22473 Charleston, WV, USA (March 5, 2015), this Court allowed Dr. Elliot, an urogynecologist, to offer degradation opinions based on his clinical experience as well as his extensive review of the scientific literature and internal Ethicon documents. Bellew at * 23 (also holding that Dr. Klinge's opinions concerning mesh degradation, fraying and particle loss were reliable because "throughout both of these sections of his expert report, Dr. Klinge supports his opinions, at least in part, by citing to peer-reviewed, published literature" including the peer-reviewed publications by Costella and Clave which, among other publications, Dr. Michaels similarly relies upon for his degradation opinions).

B. Dr. Michaels' opinions concerning degradation, embrittlement and loss of mechanical properties are reliably based on his knowledge, training and experience as well as his review of peer-reviewed publications and Ethicon's internal studies.

The Defendants again blatantly misrepresent Dr. Michaels' deposition testimony when they argue "Dr. Michaels testified that his embrittlement opinion is based solely on his 'examination of the gross specimens in the past[.]'" Def. Br. at 5. A clear reading of Dr. Michaels' expert report and deposition transcript tells a different story. As an initial matter, Dr. Michaels' expert report demonstrates that he relied on numerous peer-reviewed publications to reach his degradation opinions. See Exhibit A at 6 (Liebert 1976, Jongelbloed 1986, Mary 1998, Costello 2007, Clave 2010, Wood 2013). Dr. Michaels' expert report further demonstrates that he relied on a number of internal Ethicon documents including an internal

study conducted by Ethicon's pathologists in 1984 which shows that Ethicon's own pathologists, using the same histology methods employed by Dr. Michaels, concluded that the Prolene fibers degrade, become embrittled and crack after implanted in the human body over time. According to Ethicon's pathologist "The cracked layer appeared blue in gross specimens and **blue dye particles** were evident in histological sections of the layer. **This would indicate that the layer is dyed PROLENE polymer and not an isolated protein coating on the strands."** Exhibit F (emphasis added) (ETH.MESH.15955462). See also Exhibit A at 6; Exhibit C at 15:15-16:18; 20:12-21:1; 39:2-11; 39:21-40:17; 40:6-41:9; 48:9-49:10; 49:17-18; 52:4-12; 57:9-24; 60:14-20; 63:2-12; 64:9-65:10; 65:21-66:5; 72:15-18; 76:14-77:13; 82:5-19; 103:11-104:4.

Thus, Dr. Michaels clearly relied on the peer-reviewed publications and internal Ethicon documents in reaching his conclusions concerning degradation, embrittlement and loss of mechanical properties –methods this Court has previously determined are reliable. Additionally, Dr. Michaels also relies on his pre-litigation pathology experience as well as the histological analysis of mesh explant specimens he reviewed as an expert witness in this litigation using industry standards in his pathology field, such as histology staining and polarized light microscopy. As discussed above, this Court has previously found these methods to be reliable.

C. Dr. Michaels' use of polarized light microscopy is reliable.

The Defendants initially argue that, unlike his Wave 2 report, Dr. Michaels did not offer an opinion in his Wave 3 report that he can observe a layer of degraded Prolene using polarized light microscopy and because he failed to disclose this opinion in his Wave 3 report, he should be precluded from offering this opinion in Wave 3. However, Dr. Michaels did disclose this

opinion in his Wave 3 report and even provided polarized light microscopy images to support his opinion and to illustrate this observation. *See* Exhibit A at 26.

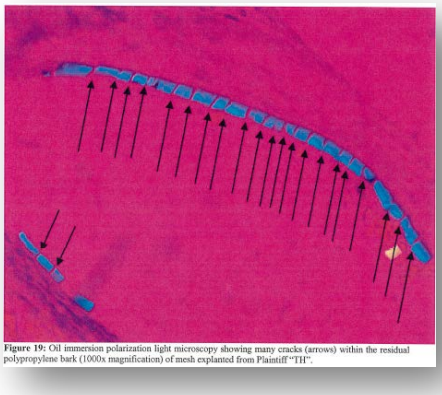

Figure 19: Oil immersion polarization light microscopy showing many cracks (arrows) within the residual polypropylene bark (1000x magnification) of mesh explanted from Plaintiff "TH".

Dr. Michaels also cited to an Ethicon internal document to demonstrate that its own pathologists similarly observed the same surface degradation found by Dr. Michaels using the same polarized light and histology methods that Dr. Michaels employed. *Id*. at 6-7. As such, the Defendants' argument in this regard should be rejected outright.

Polarized light microscopy used by Dr. Michaels to review the explant specimens for degradation has been recognized as the industry standard by this Court and has been utilized by Ethicon itself for decades. Ethicon's claim that there is no scientific or medical evidence to support Dr. Michaels' opinions concerning degradation "bark" from explanted mesh is simply wrong. Dozens of peer-reviewed articles have demonstrated that polypropylene degrades in the body. In other words, Dr. Michaels is not alone in his scientific research and his opinion in this case regarding the fact that Ethicon's Prolene degrades is overwhelming supported by the medical literature and Ethicon's own internal documents. Dr. Michaels used standard histopathology techniques including light microscopy that has been recognized for decades as a reliable method for identifying synthetic foreign materials.

Under a *Daubert* analysis, the dispositive question here is not, as Ethicon posits, whether Dr. Michaels' conclusions of degradation "bark" have been previously published in the medical and scientific literature. Instead, the appropriate question is whether Dr. Michaels utilized an established, reliable methodology when studying the explanted mesh samples and when arriving at his opinions. In previously rejecting this same argument from Ethicon, this

Court has held that "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Eghnayem v. Boston Sci. Corp.*, 57 F. Supp. 3d 658, 669 (S.D. W. Va. 2014).

This Court has already found that the same methodology used by Dr. Michaels by other pathology experts to detect degradation "bark" is reliable. See *Edwards v. Ethicon,* 2014 U.S. Dist. Lexis 92316, 69-70 (S.D. W. Va. 2014). Incredibly, the methodology used by Dr. Michaels to review the specimens for degradation – H&E staining and polarized light – are the same methodologies that have been utilized by Ethicon's own pathologists who – like Dr. Michaels - concluded that Prolene does indeed undergo *in vivo* surface degradation. Ex. A. at 8-9.

Because the methods and techniques utilized by Dr. Iakovlev are not new or novel, are widely accepted in the medical community and are well accepted in the peer-reviewed literature (and evidently, well accepted by Ethicon's own scientists well before the litigation began), his methodology is sound and his conclusions – which are consistent with those of Ethicon's own scientists – are therefore admissible.

D. The peer-reviewed publications strongly support Dr. Michaels' degradation opinions despite the Defendants' misrepresentations.

The Defendants waste a considerable amount of time arguing that Dr. Michaels' opinions are unreliable because – according to them – the peer-reviewed publications he relies upon do not actually support his opinions. Def. Br. at 8-11. This couldn't be further from the truth. Indeed, every researcher in each study relied upon by Dr. Michaels concluded that polypropylene undergoes *in vivo* degradation overtime. Yet, despite this, the Defendants argue for an opposite conclusion. For example, the Defendants argue that:

- Costello (2007): While the study found that Bard's polypropylene mesh degraded, it showed

that the Prolene Soft polypropylene mesh manufactured by Ethicon did not degrade. Defendants' argument in this regard is wholly disingenuous. In the Costello study, the Prolene Soft mesh was used only as a control. It was a pristine mesh that had not been implanted in a patient and, therefore, was not exposed to the *in vivo* environment. The Prolene Soft in the Costello study was used as a control to make sure the cleaning process to remove the tissue from the explanted Bard specimen would not cause damage or create an artifact on the explanted specimen which would be misinterpreted as degradation. While the Costello article provides strong evidence that polypropylene-based mesh devices are susceptible to *in vivo* degradation, it does not in any way support the Defendants assertion that Prolene Soft mesh does not degradation overtime when implanted in the human body.

- Wood (2013): Defendants argue that the Wood article does not support Dr. Michaels' degradation because the study may not have analyzed Prolene and involved hernia mesh, not mesh used in the pelvic floor. Like the Costello article, the Wood study provides strong support that polypropylene-mesh degrades *in vivo*.

- Jongebloed (1986): The Defendants admit the researchers found that Ethicon's Prolene suture degraded. This study provides strong support that Ethicon's Prolene-based products under *in vivo* degradation. The Defendants, however, argue that because this publication involved "ocular" Prolene sutures, it degraded from exposure to ultraviolet radiation. This study which involves the same material used in Ethicon's mesh devices provides strong evidence that Prolene is susceptible to *in vivo* degradation. The study also provides important information on how to distinguish "protein" artifact from cracked and degraded Prolene – an issue suspiciously ignored by the Defendants.

- Mary (1998): In the Mary study, the researchers compared explanted Prolene sutures to explanted PVDF sutures and concluded that Ethicon's Prolene degraded more rapidly *in vivo* than the PVDF sutures. This peer-reviewed publication provides very strong evidence that Ethicon's Prolene products degrade *in vivo*. Incredibly, however, Ethicon argues that this study doesn't support Dr. Michaels' degradation opinions because – according to Ethicon – the methodology used by these researchers was unreliable.

- Liebert (1976): Finally, Ethicon argues that the Liebert study shows that antioxidants protect polypropylene from degradation. The Liebert study demonstrates that inadequately protection will degrade cause *in vivo* degradation over time.

The studies relied upon by Dr. Michaels provide strong support that polypropylene and Prolene specifically are susceptible to *in vivo* degradation over time yet the Defendants reach the opposite conclusion. However, as this Court has previously concluded:

> I "need not determine that the proffered expert testimony is irrefutable or certainly correct" — "[a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" . . . "[t]he

> inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached."

Eghnayem v. Boston Sci. Corp., 57 F. Supp 3d 658, 669 (S.D.W. Va. 2014).

E. Dr. Michaels' degradation opinions are further supported by Ethicon's own internal documents.

Dr. Michaels also relies on numerous internal Ethicon documents which provide strong support for his degradation opinions and are consistent with the published research and Dr. Michaels' own experience analyzing explanted polypropylene mesh and suture specimens. Like the section immediately above, the Defendants argue that "none of the documents he cites actually supports his opinions." Def. Br. at 11-12. Not surprisingly, the Defendants continue to misstate and mischaracterize evidence in this case. For example, the Defendants cite to Dr. Jordi's deposition from 3 years ago to suggest that that Dr. Jordi conceded that a decrease in molecular weight of an explanted polypropylene specimen is required to prove degradation. Def. Br. at 12.

Faced with similarly misrepresentations in the past, Dr. Jordi submitted a rebuttal report wherein he stated that any attempt to suggest that he has "concluded [] in my report that no molecular weight change is equivalent to no degradation" would be "far from the truth." See e.g., Exhibit G - Jordi Rebuttal Report, 11/5/13, at 24.

As if this wasn't clear enough, Dr. Jordi further wrote that "the degradation by free radical attack is a surface phenomenon. The bulk of the polymer will not be cracked at least initially" but any suggestion that "molecular weight changes are required to prove degradation by free radical attack is illogical and misleading. Additionally, the environmental stress cracking mechanism does not require changes in the molecular weight." *Id*.

Thus, the internal Ethicon documents that Dr. Michaels relies on and which consistently demonstrate that Ethicon's Prolene degrades *in vivo* are reliable even without molecular weight data. While Ethicon's expert witnesses may disagree with the Plaintiffs' experts, this is not a basis for exclusion under *Daubert*. *Edwards v. Ethicon*, 2014 U.S. Dist. Lexis 92316, 69-70 (S.D. W. Va. 2014).

F. Dr. Michaels' opinions that degradation causes clinical complications is well supported and reliable.

Ethicon next argues that even if its mesh does degrade, Dr. Michaels cannot correlate that degradation to any clinical complications. In attempting to justify their argument, Ethicon misrepresents the state of the record, the state of the medical and scientific literature, and Dr. Michaels' own training and expertise. Ethicon is either purposefully or carelessly ignorant of this Court's prior orders that have consistently permitted pathologist, like Dr. Michaels, to testify as to the matters that are the subject of this Motion.

Dr. Michaels is qualified, by virtue of his training and experience as a clinical and anatomical pathologist to opine on the correlation between clinical complications and pathology review which are based on sound scientific and medical principles. Indeed, that is his everyday job. As this Court has previously noted in connection with a previous Ethicon *Daubert* challenge concerning another pathologist:

> A pathologist is a clinician who provides diagnoses for patient care based on the examination of specimens they receive and relevant clinical information. Dr. Iakovlev testified that "[e]verything which is taken out of the human body or taken off a human body at the time of death comes for a pathology co-examination, so we have to correlate the devices with the changes in the body, and this is part of our training as pathologists." According to Ethicon's expert Dr. Zheng vaginal mesh "just represent[s] a kind of foreign body" for a pathologist to examine. "[A] pathologist typically deals with many kinds of foreign or medical device[s] removed or explanted from patients . . . . So overall TVT or mesh-related product is part of those medical devices removed and then submit [ted] to the pathology department. The[] pathologist has

> expertise to examine them[.]" [Ethicon's Expert Dep. at 46.] Dr. Zheng has also testified that pathologists can help diagnose clinical problems, including symptoms such as pain and bleeding.

Edwards v. Ethicon, 2014 U.S. Dist. Lexis 92316, 68-79 (S.D. W. Va. 2014). Dr. Michaels' job requires him to have "frequent interactions with clinical colleagues in the day to day management of patients." Dr. Michaels testified that as a diagnostic clinical pathologist his:

> [M]ain purpose in reviewing these slides is to correlate my microscopic findings with the clinical indication for the surgical removal of mesh. And to generate a pathologic differential diagnosis with regards to what the clinical indications was for the surgery and with what I'm seeing histologically and to rule out other causes that could have influenced the patient's infection, or pain or dyspareunia, or whatever – erosions, whatever else could have influenced that.

Exhibit C at 82:5-14.

Elaborating further, Dr. Michaels testified that his goal as a pathologist is to "evaluate the types of materials that I see pathologically and to correlate whatever histopathologic responses I'm seeing to whatever material with what's going on clinically." Thus, by virtue of his education, training and experience as a clinical pathologist, Dr. Michaels is qualified to testify about the correlation between explanted mesh pathology and clinical complications; the potential injuries to the female body from Ethicon's mesh; and the correlation between mesh and pain in patients.

According to Dr. Michaels:

> The clinical significance with respect to degradation is that once you're degrading a foreign body and it breaks apart, there's a greater surface area now that the foreign body that's in connection and in affiliation with the tissue. So that would increase the inflammatory response, because now you have new foreign antigens that are in, I guess, direct contact with the tissue.
>
> That would then increase the inflammatory response, and that increased inflammatory response would potentially or likely, given the severity of it, lead to additional damage to

> the remaining polypropylene or foreign material. And then that would then lead to more breakdown and more degradation, which would then turn into this, you know, basically a cyclical phenomenon where you have a feedback loop that's just constantly going, contributing, to greater amount of inflammation and scarring.

Exhibit C at 58:9. Dr. Michaels testified that these pathological features would then correlate with other clinical symptoms. *Id.* at 59:19-60:3. And Dr. Michaels cited to peer-reviewed publications in his expert report that further support this opinion. See Exhibit A at 6.

Any criticisms the Defendants may have concerning Dr. Michaels' inability to specifically recall the name of any study he relied upon or disagreements Ethicon may have concerning Dr. Michaels' interpretation of the studies is mere fodder for cross examination. Because Dr. Michaels' opinions are reliable, Ethicon's motion in this regard should be denied.

II. Dr. Michaels' Opinions Regarding Contraction, Shrinkage, and Deformation of Ethicon Mesh Products Are Reliable.

Ethicon argues that Dr. Michaels should be precluded from offering opinions concerning mesh contraction, shrinkage, and deformation of Ethicon mesh products because he failed to follow the standard methodology used by pathologists for determine how a specimen is oriented in the human body. The Defendants argument fundamentally misunderstands Dr. Michaels' role as a diagnostic anatomical pathologist and also fails to recognize that Dr. Michaels' opinions are based on multiple sources, including his review of the published literature and his own experience. Exhibit C at 39:21-40:17. Moreover, Dr. Michaels uses "standard histology techniques" when he analyzes mesh explant specimens and has been trained to specifically identify artifacts: "as a pathologist, you can identify when there are folds in the tissue as opposed to something that is occurring biologically or pathologically." *Id.* at 50:24-51:8.

But Dr. Michaels doesn't just rely on one source of his opinions: "[w]hen I form an opinion it's based on everything, it's not based on just one thing." *Id.* 49:17-18. This is why

Dr. Michaels also relied on peer-reviewed publications and Ethicion's internal documents within his expert report that support his contraction, shrinkage, and deformation opinions. See Exhibit A at 1-6. See also Exhibit H - Dr. Michaels' Reliance List. As Dr. Michaels testimony demonstrates, he considers both sides of a disputed issue. *Id*. 48:6-15. Dr. Michaels' mesh-contraction, shrinkage and deformation opinions are sufficiently reliable under Daubert and this Court has allowed "numerous pathologists to testify regarding the properties of polypropylene mesh" who used the same methodology used by Dr. Michaels here. *Eghnayem*, 57 F. Supp. 3d 658, *5–9 (S.D. W. Va. 2014), (citations omitted).

III. Dr. Michaels' Opinions Regarding The Complications Caused By Ethicon's Mesh Devices Are Reliable.

The Defendants again mischaracterize Dr. Michaels' testimony by suggesting he does not understand mechanisms of inflammatory response. Def. Br. at 15-16. This is yet another example of Ethicon taking a sentence out of context to mischaracterize Dr. Michaels' opinions. What Dr. Michaels actually said was: "I would say the mechanisms with regard to inflammation and pain is something that is extremely complex and not something that I, as a pathologist generally would report or describe. Simply correlating the fact that inflammation is known to be associated with pain and reporting whether that inflammation is present or not, but not with regards to the receptors and the cytokines that are produced and the feedback loops and cycles…." Exhibit C at 98:14-23. Dr. Michaels goes on to explain in great detail the mechanism of action of inflammation demonstrating his eminent qualifications to offer this reliable opinion. *Id*. at 99:11-100:9.

The Defendants also argue that Dr. Michaels' opinions are unreliable because – according to the Defendants – Dr. Michaels' opinions are contradicted by the Hill publication. Dr. Michaels testified that he considered the Hill article but articulated several reasons why he felt the Hill article was flawed – weaknesses that the authors themselves recognized. Def. Br. – Exhibit DD, A. Hill, et al. *Histopathololgy of Excised Midurethra Sling Mesh,* 26 Int'l Urogynecology J. at 594-595.

This Court has ruled throughout the mesh MDLs that pathologists are qualified to offer opinions concerning complications caused by Ethicon's mesh products. For example, in *Sanchez v. Ethicon*, this Court denied Boston Scientific's similar argument concerning Dr. Trepeta. In denying Boston Scientific's motion, this Court held:

> Again, Dr. Trepeta's extensive experience and knowledge in the field of pathology qualify him to submit these opinions. Part of pathology involves reaching a diagnosis through "clinical and pathologic correlation." (*See id*. at 11:10-14). Dr. Trepeta frequently engages in this process by providing clinical consultations to physicians, which require him to examine clinical information (through specimens, reports, [*53] or physician findings) and reach a pathologic diagnosis about a patient. (*See id*.). Dr. Trepeta applied this pathologic process in reaching his conclusions about the human clinical responses to polypropylene vaginal mesh. He examined fifty pathology samples from mesh removals and opines that he observed injuries "consistent with the pathological process of tissue response and/or injury due to polypropylene." (Trepeta General Report [Docket 86-1], at 2). He also compared medical literature to these observations and concluded that his pathological findings "are well described in the published literature." (*Id*.). Dr. Trepeta's understanding and application of the pathologic process qualify him to opine on the causal relationship between transvaginal mesh implantation and tissue response.[4] Therefore, I **DENY** BSC's motion on this point.

Sanchez at *52-53. As discussed in detail above, Dr. Michaels applied the identical methodology applied by Dr. Trepeta in reaching his opinions concerning the types of complications caused by Ethicon's mesh products.

IV. Dr. Michaels' Opinion That Pain Can Be Caused By Nerve Entrapement Within The Mesh Pores Or Scar Plate Is Reliable.

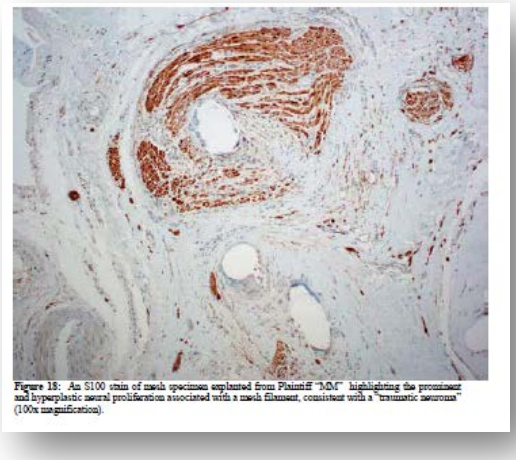
Figure 18: An S100 stain of mesh specimen explanted from Plaintiff "MM" highlighting the prominent and hyperplastic neural proliferation associated with a mesh filament, consistent with a "traumatic neuroma" (100x magnification).

The Defendants argue that, unlike his Wave 2 report, Dr. Michaels did not offer an opinion in his Wave 3 report that "the presence of a nerve in scar tissue or its proximity to mesh fibers are sufficient to conclude that a patient suffered from pain" and that because he failed to disclose this opinion in his Wave 3 report, he should be precluded from offering this opinion in Wave 3. Def. Brf. at 17. However, Dr. Michaels did disclose this opinion in his Wave 3 report and even provided microphotograph images to support this opinion and to illustrate his observation. *See* Exhibit A at 5, 23-25.

Dr. Michaels also cited to peer-reviewed publications supporting this opinion. *Id*. at 5 (citing Firoozi 2012; Crosby 2014; Danford 2015). As such, the Defendants' argument in this regard should be rejected.

Similarly, Ethicon misrepresents the record to the Court when it asserts that Dr. Michaels cannot support his opinions that the distortion and entrapment of nerves in mesh material and scare causes pain. Def. Br. at 17. Not only is this opinion not "novel" as Ethicon asserts but Dr. Michaels cited to numerous peer-reviewed publications that support these opinions. *See e.g.*, Exhibit A at 5. Furthermore, Dr. Michaels has provided actual proof

in the form of pathology slides from explanted mesh that demonstrate that Ethicon's mesh becomes encapsulated in scar tissue, deforms and entraps nerves within the mesh and mesh-scar complex. Dr. Michaels also relies on his review of the medical records and deposition testimony and correlates his pathological findings with the clinical indication for mesh removal which provides Dr. Michaels with additional objective evidence to support his opinions. Exhibit C at 82:5-14. The fact that Ethicon has embellished its *Daubert* motion with conflicting opinions asserted by its own paid experts is of no import to this motion and is not a valid argument under *Daubert* for exclusion of these conflicting opinions.

V. Dr. Michaels Will Not Offer Opinions Concerning Ethicon's Knowledge, State of Mind, And Corporate Conduct.

The Defendants' last argument is that Dr. Michaels should be precluded from offering opinions concerning Ethicon's knowledge, state of mine, and corporate conduct. The Plaintiffs recognize that this Court has ruled that expert witnesses cannot offer these types of opinions and Plaintiffs will abide by the Court rulings in this regard. However, Dr. Michaels relies on several Ethicon internal documents for other permissible purposes. For example, Dr. Michaels relies on several internal documents to support his opinions that Prolene degrades or that Ethicon's Prolene mesh devices contract, shrink, and deform. Thus, while Dr. Michaels relies on numerous Ethicon documents and employee depositions, Dr. Michaels will not offer opinions concerning Ethicon's knowledge, state of mind, and corporate conduct but instead relies on these internal corporate documents to support his opinions concerning causation.

CONCLUSION

Dr. Michaels is eminently qualified as a board certified diagnostic pathologist to offer his general opinions concerning the properties of mesh, including the propensity for Ethicon's Prolene mesh to degrade and to causing complications to patients as discussed in detail above.

Moreover, Dr. Michaels' opinions are reliable and overwhelmingly supported by the published literature and Ethicon's own internal documents. As such, the Defendants' motion to exclude Dr. Michaels should be denied in its entirety.

Dated: October 10, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 10, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

Respectfully submitted,

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